REMARKS

The following remarks are believed responsive to the points raised by the Office Action dated June 10, 2003. In view of these remarks, reconsideration is respectfully requested.

The Pending Claims

Claims 1, 2, 4-7, 9-14 and 17-25 remain pending.

The Office Action

Claims 1, 2, 4-7, 9-14 and 17-25 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,587,070 to Pall *et al.* (hereinafter referred to as " Pall 070"). This rejection is respectfully traversed.

The Office Action acknowledges that Pall '070 does not teach, disposed in a single housing, either a first filter element comprising a porous fibrous leukocyte depletion medium having a CWST of at least about 70 dynes/cm, and a second filter element comprising a porous membrane having a pore size of about 5 micrometers or less, or a first filter element comprising a porous fibrous red cell barrier medium and a leukocyte depletion medium having a CWST of at least about 70 dynes/cm, and a second filter element comprising a porous membrane having a pore size of about 5 micrometers or less.

However, the Office Action states that Pall '070 teaches a filter comprising a porous fibrous leukocyte depletion medium having a CWST of greater than 70 dynes/cm, and teaches a filter of 5 microns or less, and concludes it would have been obvious to one of ordinary skill in the art at the time of the invention to put a fibrous leukocyte depletion filter and a membrane in the same housing in series to obtain the desired separation of biological fluids while reducing the volume hold-up of the biological fluids. The Office Action also refers to compactness, ease of fabrication, and less conduit length.

The Office Action's position is incorrect.

While Pall '070 refers to a porous fibrous leukocyte depletion medium and a membrane (the Office Action has noted references to a membrane as a separation medium in the non-centrifugal separation device), there is no suggestion of placing them in the same housing. Rather, as applicants have indicated in the previous response, '070 Pall discloses the media in separate devices, e.g., at col. 18, lines 43-50: "In the embodiment of the invention which includes a separation assembly **14**, preferably a non-centrifugal separation device, the supernatant layer (e.g., PRP) may be passed through a leucocyte depletion assembly, and then

passed through the non-centrifugal separation device **14**, where it may be processed and separated into components. . ." *See also*, Figure 2, showing separation assembly **14**, separate from a first leucocyte depletion assembly **13**.

One reading Pall '070, that discloses fibrous leukocyte depletion media and membranes in separate devices, would not be led to include both media in a single device, and would not be led to process a biological fluid by passing it through such a device. In accordance with Pall '070, the leukocyte depletion assembly (which includes a leukocyte depletion medium) is disclosed as being a distinct device from the non-centrifugal separation device (which includes a membrane) because, as is known in the art, the devices are operated differently.

In accordance with Pall '070, biological fluid passes through the leukocyte depletion medium of a leukocyte depletion assembly wherein the fluid passes through the upstream surface and through the downstream surface of the medium. Fluid does not pass tangentially or parallel to the upstream surface, it passes through the downstream surface (*see*, for example, Figure 2, wherein the filtered fluid passes through the single outlet of first leukocyte depletion assembly **13**). Biological fluid passes through the red cell barrier medium of the red cell barrier filter assembly in a similar manner (*see*, for example, Figure 2, wherein the filtered fluid passes through the single outlet of red cell barrier assembly **12**).

As explained in Pall '070 with respect to the separation device, the biological fluid flows tangential or parallel to the separation medium and clogging by other components is minimized or prevented (*see*, for example, col. 18, lines 40-42; col. 20, lines 38-40, *see also*, Figure 5 illustrating the tangential flow and first and second outlets **212** and **213**). Thus, plasma passes through the membrane (through the upstream and downstream surfaces), and other components pass parallel or tangential to the upstream surface without passing through the downstream surface of the membrane.

This is further reinforced by the portion of Pall '070 specifically relied on in the Office Action as supporting the Office Action's conclusion (*see*, page 7 of the Office Action, referring twice to col. 10, lines 21-39 of Pall '070). As stated at col. 10, lines 21-39: "Tangential flow of a biological fluid parallel to the upstream surface of the separation medium permits the passage of plasma through the medium, while reducing the tendency of cellular components or platelets to adhere to the surface of the medium, thus assisting in the prevention of passage of platelets through the separation medium. The hydrodynamics of flow parallel to the surface are indeed believed to be such that during flow parallel to the surface, platelets develop a spin which causes them to be recovered from the surface."

Thus, as explained above, plasma passes through the membrane (through the upstream and downstream surfaces), and other components pass parallel or tangential to the upstream

surface without passing through the downstream surface of the membrane. One of ordinary skill in the art would not be led to include a fibrous leukocyte depletion medium or a fibrous red cell barrier in the separation device containing the membrane as such a fibrous medium would interfere with the flow tangential or parallel to the upstream surface of the membrane, thus leading to clogging.

Accordingly, the Office Action has failed to provide a *prima facie* case of obviousness in regard to the present invention.

The portion of Pall '070 cited by the Office Action as supporting the statements about hold up volume (col. 28, lines 45-52) discloses the use of gas to facilitate the recovery of biological fluid trapped during processing (*see*, col. 28, lines 56-58), and does not lead one to combine a fibrous leukocyte depletion medium and a membrane in a single device or to combine a fibrous red cell barrier medium and a membrane in a single device. While the Office Action refers to reducing volume hold-up as the rationale for modifying Pall '070, one of ordinary skill in the art would not be led to the modification stated in the Office Action to reduce the hold up volume. Including a fibrous leukocyte depletion medium or a fibrous red cell barrier medium in the separation device with the membrane would, in view of the increase in clogging as explained above, adversely impact the operation of the device, if not rendering it inoperative. Furthermore, it would not reduce the hold up volume.

Applicants again submit the rejection of the present claims can only be made by utilizing the present invention as a guide and employing improper hindsight analysis. Applicants note the Office Action indicates *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991) "is about combining a large number of references in order to support a rejection of obviousness" and "has no bearing on this case." Applicants respectfully submit that, regardless of the number of references applied, the proper basis for a rejection comes from a suggestion or motivation from the prior art, not the claimed invention itself. For the reasons set forth above, Pall '070 does not provide the teachings whereby the claimed invention would have been obvious.

For the reasons set forth above, reconsideration is respectfully requested.

Conclusion

In view of the remarks recited herein, the application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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Amendment or ROA - Regular (Revised 7/29/03)